UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,872	10/22/2003	Jane Hirsh	CP 107P	6830

23579 7590 01/31/2008

PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE, SUITE 1200
1201 PEACHTREE STREET
ATLANTA, GA 30361

EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
01/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/690,872	Applicant(s) HIRSH ET AL.	
	Examiner Leah Schlientz	Art Unit 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 January 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *03 January 2008*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-4, 6-12 and 14-22*.

   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 7.

Claims 1, 4 and 14 have been amended. Claims 5, 13 and 23 - 24 have been cancelled. Claims 1-4, 6-12 and 14-22 are pending.

The rejeciton of claim 13 under 35 USC 112, second paragraph, has been withdrawn in view of claim cancellation.

Claims 1 - 4, 6 - 10, 15 - 17 and 19 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha in view of Ansseau for reasons set forth in the Office Action mailed 3/26/2007.

Applicant argues that the combined teachings of Midha in view of Ansseau do not disclose or suggest a pulsatile release milnacipran formulation which provides a therapeutic effect over 24 hours with reduced incidence of intensity of side effects.

This is non-persuasive because Midha teaches that pulsatile release formulations, including those having a release profile within the claimed range, are useful for drugs which have a short half-life and must otherwise be administered two or three times daily (column 1, lines 18+). One would have been motivated to provide milnacipran in such a pulsatile release dosage form because Ansseau specifically teaches that milnacipran has only a 7 hour plasma elimination half-life, and has previously been administered in two divided daily doses (page 136). The limitations such as reduced incidence or severity of side effects are functional in nature and would be an inherent property of such a formulation. The instant claims are defined only by function and are devoid of any structural limitations which might be used to distinguish over the cited references. Cmax values of a given drug are also inherent properties of a given formulation. In the absence of evidence to the contrary, it is interpreted that the combined teachings of the pulsatile release formulation of a drug having a short half life, which must otherwise be provided in two separate doses, such as milnacipran, would be capable of the claimed release profile because the pulsatile release formulations taught by Midha are achieved via the same coatings, etc. Regarding Applicant's argument that milnacipran does not exhibit potential for abuse, this is not found persuasive because Midha only teaches that pulsatile release formulations are useful for drugs having short half-lives which must be administered two or three times daily, and that such formulations are also useful for minimizing the abuse potential of certain types of drugs, however, Midha does not exclusively teach that only drugs having both qualities (i.e. short half-life and potential for abuse) are necessary. Regarding applicant's contention that Midha teaches away from a formulation having a therapeutic effect over 24 hours, this is not found persuasive because Midha only teaches reduced dosage at night, and does not teach a complete lack of therapeutic effect at night.

With regard to arguments addressed to the declaration filed 1/3/2008, such arguments have not been considered at this time because the affadavit has not been entered. See section 8 of Advisory Action.

Claims 1- 4, 6 -10 and 15 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha in view of Ansseau, in further view of Menza for reasons set forth in the Office Action mailed 3/26/2007.

Applicant argues that the combined teachings of Midha in view of Ansseau do not disclose or suggest a pulsatile release milnacipran formulation which provides a therapeutic effect over 24 hours with reduced incidence of intensity of side effects, and that Menza does not provide the elements missing from Midha and Ansseau.

This is non-persuasive for reasons set forth above, and because Menza teaches that modafinil is an augmenter to antidepressants in the treatment of depression.

Claims 1 - 12, 15 - 17 and 19 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha in view of Ansseau, in further view of Paillard for reasons set forth in the Office Action mailed 3/26/2007.

Applicant argues that the combined teachings of Midha in view of Ansseau do not disclose or suggest a pulsatile release milnacipran formulation which provides a therapeutic effect over 24 hours with reduced incidence of intensity of side effects, and that Paillard does not provide the elements missing from Midha and Ansseau.

This is non-persuasive for reasons set forth above, and because Paillard teaches that cis and trans enantiomers may be used in modafinil formulations for the treatment of depression.

Claims 1 - 3, 6 - 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al. (US 2003/0203055) for reasons set forth in the Office Action mailed 3/26/2007.

Applicant argues that Rao does not disclose a pulsatile release formulation, citing that "Example 41 in Rao describes a formulation containing an immediate release and sustained release doses." Applicant further contends that "a pulsatile release formulation is characterized by a first does of drug followed by a period of no release, followed by release of a delayed release dose, etc."

This is non-persuasive because Rao teaches a multilayer tablet having an immediate release portion and a sustained release portion. In the absence of evidence to the contrary, such a formulation would result in at least one "pulse" of the active ingredient upon dissolution of the immediate release layer of the tablet, and then at least some additional release of active agent upon dissolution of the delayed release portion of the multilayer coatings. The instant claims are defined only by function and are devoid of any structural limitations, other than that the composition comprises a coating, which is also present in the formulations taught by Rao et al.

The obviousness-type double patenting rejections are maintained for reasons of record.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER